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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/871,146	05/25/2001	Anthony E. Bolton	033136-182	8192

7590

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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT

PAPER NUMBER

1649

DATE MAILED: 08/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/871,146

Applicant(s)

BOLTON ET AL.

Examiner

Olga N. Chernyshev

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1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 16-19 and 47-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 19, 47, 48 and 54 is/are allowed.
- 6) ☒ Claim(s) 16-18, 49-53 and 55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/10/5: 1/21/5</u> | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

### ***Formal matters***

1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1649.

### ***Response to Amendment***

2. Claims 16-19 and 49 have been amended, claims 33-46 have been canceled and claims 53-55 have been added as requested in the amendment filed on June 23, 2005. Following the amendment, claims 16-19 and 47-55 are pending in the instant application.

Claims 16-19 and 47-55 are under examination in the instant office action.

3. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Applicant's arguments filed on June 23, 2005 have been fully considered. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn. Applicant's amendment necessitated the new ground(s) of rejection, which is set forth in this Office action.

### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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6. Claims 16-18, 49-50 and 52-53 are rejected under 35 U.S.C. 102(b) as being anticipated by Herrmann et al., 1998 (Arthritis & Rheumatism, Vol. 41, No. 7, pp.1241-50).

Claims 16-18, 49-50 and 52-53 are directed to pharmaceutical compositions comprising a pharmaceutically acceptable excipient and human cellular composition comprising apoptotic bodies and/or apoptotic cells. Publication of Hermann et al. teaches suspension of human peripheral blood mononuclear cells (PBMC), cultured *in vitro*, during which time the cells underwent spontaneous apoptosis (see page 1243, first column). The medium used to culture PBMC is compatible with physiological conditions, and not incompatible with pharmaceutical use. Since the instant specification does not provide any limiting definitions of pharmaceutically acceptable excipient, the prior art's culture medium would appear to be encompassed by the broadest reasonable definition of a "pharmaceutically acceptable excipient". Further, one skilled in the art readily appreciates that during culture, some of the cells would naturally undergo necrosis, therefore certain percentage (less than 10%) of the cultured white blood cells in suspension of Hermann et al. would represent necrotic bodies (see claims 16-17 and 53), and most of the cells would be viable (see claim 49).

7. Claims 16-18, 49-50 and 52-53 are further rejected under 35 U.S.C. 102(b) as being anticipated by Bartholeyns et al, 1998 (Res. Immunol., 149, pp.647-649).

Applicant is advised that due to the use of open language in the claims (composition [...] "comprising" [...] "cellular composition comprising", as in claim 16, for example), and also in view of the indefiniteness of the claim language as explained in sections 10-12 of the instant office action, the instant claims by broadest reasonable interpretation read on most autologous cellular vaccines, which are prepared by processing patient's own white blood cells outside of

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the patient's body and further treated with necrotic cells and apoptotic cells/bodies (see summary and the whole paper of Bartholeyns et al.). Thus, absent evidence to contrary, autologous cellular vaccine of Bartholeyns et al. meets the limitations of the instant claims 16-18, 49-50 and 52-53.

***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 16-18, 49-53 and 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claim 16, as amended and claim 53 are vague and indefinite for recitation "said cellular composition is suitable for administration". Because the claims recite two compositions, "a pharmaceutical composition" and "human cellular composition", it is not clear and cannot be determined from the claims, which of the compositions is intended for administration.

Clarification is required.

11. Claim 18 is vague and ambiguous for recitation "wherein said apoptotic bodies and/or cells are derived from the patient's own body". Normally patient's body contains a limited amount of apoptotic cells; therefore, it is not clear if the claim recites the apoptotic cells derived from patient's body, or the cells from patient's body, which were later treated to undergo apoptosis. Clarification is required.

12. Claims 17, 49-52 and 55 are indefinite for being dependent from indefinite claims.

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***Conclusion***

13. Claims 16-18, 49-53 and 55 are rejected, claims 19, 47-48 and 54 are allowed.
14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Olga N. Chernyshev, Ph.D.  
Primary Examiner  
Art Unit 1649

August 16, 2005